

## Medication Information Sheet

**daBRAFe-nib** (da-BRA-fe-nib)

*This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.*

**Other Name:** Tafinlar®

**Appearance:** capsule In various strengths and colours

**What is this medication for?**

- Given alone or in combination with another medication for treating a type of skin cancer called melanoma, that has spread to other parts of the body or cannot be removed by surgery
- Given with another medication for treating a type of non-small cell lung cancer

**What should I do before I have this medication?**

- Tell your doctor and pharmacist if you have or had significant medical condition(s) such as:
  - ◊ heart rhythm, liver or kidney problems,
  - ◊ diabetes,
  - ◊ a deficiency in glucose-6-phosphate dehydrogenase enzyme,
  - ◊ or any allergies.

**How will this medication affect sex, pregnancy and breastfeeding?**

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding
- If there is ANY chance that you or your partner may become pregnant, you and your partner together must:
  - ► **Use 2 effective forms of birth control at the same time** while receiving this drug. Do not use hormonal birth control (for example, birth control pills); it may not work as well since it can interact with dabrafenib. Keep using birth control until **4 weeks** after the last dose. Discuss this with your healthcare team.
- Do not breastfeed while taking this drug.
- This medication may affect fertility (ability to get pregnant)

## How is this medication given?

- This medication is usually taken twice a day, around 12 hours apart.
- Swallow whole with a glass of water on an empty stomach, at least one hour before or two hours after food or other medications.
- Do not crush, chew or open the capsules.
- If a dose is missed, take it if there are more than 6 hours before the next dose. Otherwise, skip this dose and give the next one as scheduled. Never take both doses at the same time.

## What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. They may increase side effects.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

### For mild aches and pain or fever:

- If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
- You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
- Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
- **If you do not have any instructions on managing fever and your temperature is higher than 38.3°C, get emergency help right away.** See "Fever" in the side effects section below for more information.

## How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from

heat and light. Keep out of sight and reach of children and pets.

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

## What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
<b>Very Common Side Effects (50 or more out of 100 people)</b>	
<b>High blood sugar</b> <ul style="list-style-type: none"> <li>• You may feel thirsty and pee more often.</li> <li>• Your doctor may check your blood sugar level. You may be advised to change your diet or take medication to treat high blood sugar.</li> <li>• Check your blood sugar regularly if you have diabetes.</li> </ul>	Contact your health care team as soon as possible

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<b>Salt imbalances</b> It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.	Get emergency medical help right away
<b>Thickening of the outer layers of the skin</b>	Contact your health care team if no improvement or if severe
<b>Headache; mild joint, muscle pain or cramps</b> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<p><b>Fever (not related to infection)</b></p> <ul style="list-style-type: none"> <li>• Dabrafenib can cause fever, including high fever (more than 40°C). It may be severe with chills, shaking, too much fluid loss, low blood pressure or kidney problems.</li> <li>• Your doctor will tell you what to do with fever that may be due to dabrafenib. For mild fever, you may be instructed to take acetaminophen (Tylenol®) as directed.</li> <li>• If you do not have any instructions on managing fever and your temperature is higher than 38.3°C, get emergency help right away.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Hair thinning or loss</b></p> <ul style="list-style-type: none"> <li>• Use a gentle soft brush and avoid hair sprays, bleaches, dyes and perms.</li> <li>• In most cases, your hair will grow back after treatment, but the texture or colour may change.</li> </ul>	<p>Talk to your health care team if this bothers you</p>
<p><b>Nausea and vomiting (generally mild)</b></p> <p>May occur in hours to days after your treatment.</p> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take anti-nausea medication(s) as prescribed to you by your doctor.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (e.g. coffee, tea) and alcohol.</li> <li>• Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting.</li> </ul> <p>Also see <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<p><b>Second or new cancers (may be severe; may affect the skin or other organs)</b></p> <ul style="list-style-type: none"> <li>• Check your skin on a regular basis for any unusual skin changes (skin sores that do not heal; mole which is growing, changing shape or colour or has an irregular border).</li> <li>• Your doctor may inspect your skin regularly in case a cancer lesion would develop.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<p><b>Abnormal liver lab tests</b></p> <ul style="list-style-type: none"> <li>You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens.</li> <li>Your doctor may monitor your liver regularly with a blood test.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Fatigue (tiredness)</b></p> <ul style="list-style-type: none"> <li>Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise.</li> <li>Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less).</li> <li>Avoid driving or using machinery if you are feeling tired</li> </ul> <p>See our <a href="#">Fatigue</a> pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p><b>Hand-foot syndrome</b></p> <p>You may have pain, thinning, reddening, tingling, numbness and peeling of the skin on your palms or the soles of your feet.</p> <p>This may occur days to weeks after the dose is given or after you start treatment.</p> <p><b>To help prevent Hand-foot syndrome :</b></p> <ul style="list-style-type: none"> <li>Avoid activities that cause rubbing, pressure or heat exposure to hands and feet (i.e. gripping tools, vigorous washing and hot baths).</li> <li>Apply moisturizer often to your hands and feet, especially in the skin folds.</li> <li>Wear loose, comfortable footwear and clothes. Rest and try to keep off your feet.</li> </ul> <p>Also see <a href="#">Hand-Foot Syndrome</a> pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p><b>Rash; dry, itchy skin</b></p> <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p> <p><b>To prevent and treat dry skin,</b></p> <ul style="list-style-type: none"> <li>Use skin moisturizer.</li> <li>Protect your skin from the sun and the cold.</li> </ul>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<ul style="list-style-type: none"> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> </ul>	
<p><b>Sore throat, stuffy nose; cough, feeling short of breath</b></p> <p><b>If you have chest pain, trouble breathing or cough up blood, get medical help right away.</b></p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Diarrhea</b></p> <p>May happen days to weeks after you get your treatment.</p> <p><b>If you have diarrhea :</b></p> <ul style="list-style-type: none"> <li>• Take anti-diarrhea medication if your health care team prescribed it.</li> <li>• Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol.</li> <li>• Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>• Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy.</li> </ul> <p>See the <a href="#">Diarrhea</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Mild swelling in arms and legs; puffiness</b></p> <p><b>To help prevent swelling :</b></p> <ul style="list-style-type: none"> <li>• Eat a low-salt diet.</li> <li>• Avoid tight fitting clothing.</li> </ul> <p><b>If you have swelling in your legs, keep your feet up when sitting.</b></p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Constipation</b></p> <p><b>To help prevent constipation :</b></p> <ul style="list-style-type: none"> <li>• Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise.</li> <li>• Be Active. Exercise can help to keep you regular.</li> <li>• Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you.</li> </ul> <p><b>To help treat constipation :</b></p>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<ul style="list-style-type: none"> <li>If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do.</li> </ul> <p>See the <a href="#">Constipation</a> Pamphlet for more information.</p>	
<p><b>Low appetite</b></p> <ul style="list-style-type: none"> <li>You may not feel like eating or you may lose weight.</li> <li>Try to eat foods that you like and eat small meals throughout the day.</li> <li>You may need to take meal supplements to help keep your weight up.</li> <li>Talk to your health care team if you have a low appetite.</li> <li>See our <a href="#">Loss of appetite</a> pamphlet for more information.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

**Other rare, but serious side effects are possible.**

**If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:**

- Unusual changes in your skin
- Any changes in your vision
- Signs of bleeding such as black stools, coughing up blood, purple or red dots on skin, bleeding that will not stop
- Irregular heartbeat, chest pain, fainting, swelling in your legs, ankles or belly
- Pain in your belly that extends to your back
- Pain, swelling or hardening of a vein in your arm or leg
- Lower back pain, passing little or no urine, or recent unusual weight gain
- Signs of an allergy such as severe rash, itchiness, swollen face, lip or tongue, chest or throat tightness

For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://www.cancercareontario.ca/symptoms).

*The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.*

*A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*